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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,464	10/29/2003	Mathai Mammen	P-142-US1	5983

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EXAMINER	
CHANG, CELIA C	
ART UNIT	PAPER NUMBER
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,464	MAMMEN ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' filing of a petition to the restriction requirement has been decided and a grant in part was mailed Nov. 8, 2006.

An amendment and response to the office action dated May 31, 2006 were filed by applicants dated Aug. 10, 2006. The amendment and response were entered and considered in accordance with the grant-in-part of the restriction modification.

Claims 34-38, 40-43 (group X), and 46 have been canceled. Claims 1-33, 39, 44-45 wherein p=1, newly modified group I, continued to be examined (see previous office action, p.3, 4th paragraph). Claims 1-33, 39, 44-45 wherein p=2, newly modified group II continued to be withdrawn from consideration.

2. The rejection of claims 40-43 under 35 USC 112 second and first paragraph in the previous office action, are dropped in view of the cancellation of the claims.

3. The rejections of claims 1-33, 39, 44-45 of the previous office action are moot in view of the following new ground of rejection.

(A) Claims 1, 20, 25, 30-33, 39, and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 26, lines 15-20 of the specification it was described that "*The term solvate refers to a complex or aggregate formed by one or more molecules of a solute, i.e. a compound of formula I or a pharmaceutically-acceptable salt thereof, and one or more molecules of a solvent. Such solvates are typically crystalline solids having a substantially fixed molar ratio of solute and solvent. Representative solvents include, by way of example, water, methanol, ethanol, isopropanol, acetic acid and the like. When the solvent is water, the solvate formed is a hydrate.*"

Such disclosure provides insufficient enablement for the claimed scope of "all solvates". The specification contains none of the compound , which is a solvate. While a pharmaceutical addition salt can be prepared routinely upon in possession of an acidic or basic compound, the

solvate formation is the innate nature of a compound upon contacting certain solvent. *Without any description of what solvent will form solvate* with which compound and completely silent of the existence of any solvate or hydrate, the specification offered mere language rather than possession or enablement of the solvates and the process of the disclosure failed to provided any enablement for a solvate or hydrate.

(B) Claims 1-33, 39, 44-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22, 28-29, 33-35 of copending Application No. 10/888,855 in view of Wermuth supplemented with Pratesi CA70:37081 and Laeckmann et al.

Determination of the scope and content of the claims

The instant claims are drawn to pyrrolidinyl piperidinyl compounds with a diphenylamido methyl substituent on the pyrrolidinyl ring with linker R^1N to a piperidinyl core system.

Ascertainment of the difference between the copending claims

The difference between the instant claims and the copending claims is that the instant claims requires a pyridinyl/pyrimidinyl methylene substitution of the piridinyl ring nitrogen while the copending claims are drawn to phenylmethylene substitution at the same position with every elements of the remaining structure being identical i.e. especially compare the elected species with copending claims on p.124, line 36-37.

Finding of prima facie obviousness—rational and motivation

Phenyl and pyridinyl/pyrimidiny have been known to be isosteric structure conventionally employed as interchangeable unit for a proven compound as variation for obtaining analogous drugs (see Wermuth p.203-213, supplemented with Laeckmann et al.). Such conventional bio-isosteric replacement has particularly been applicable to affinity of choline biological system i.e. muscarinic binding which is the biological activity of the instant compounds (see Pratesi et al. CA 70:37081).

Applicants argued that SN 10/888,855 has a later filing date but provided no reason why applicants' are entitled to prolonged protection through the well known variation of the instantly claimed and elected species. In addition, applicants have filed a petition with the rational that modification of the terminal moieties is not a structural "independent and distinct" invention. Furthermore, the filing of a terminal disclaimer is not limited to extension of time but also to the unnecessary harassment by multiple assignees were the patents not commonly owned.

(C) Claims 1-33, 39, 44-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 18-20 of copending Application No. 10/975,657 in view of Berge et al. supplemented with CA 60:74793.

Determination of the scope and content of the claims

The instant claims are drawn to pyrrolidinyl piperidinyl compounds with a diphenylamido methyl substituent on the pyrrolidinyl ring with linker R^1N to a piperidinyl core system.

Ascertainment of the difference between the copending claims

The difference between the instant claims and the copending claims is that the copending claims are species of the instant claims with a pharmaceutical acceptable naphthyl disulfate salt. Napsylate (see Berger p. 2, table 1, right column, line 13) is a FDA approved commercially marketed pharmaceutically acceptable salt conventionally employed to prepare acid addition salts of drugs. (see Berger supplemented with napsylate chemical structure by CA 60).

Finding of prima facie obviousness—rational and motivation

In absence of unexpected result, there is nothing unobvious in choosing a FDA approved, commercially marketed pharmaceutically acceptable salt of the instant claims, i.e. the copending salt is an obvious variation of species among the genus of "pharmaceutically acceptable salt" of the instant claims. Especially, applicants have traverse the species restriction and alleged that all species are variation of the genus, thus, a prima facie obvious conventional pharmaceutically acceptable salt would be an obvious species within the scope of the instant generic and species claims. Applicants provided no good reason that why applicants are entitled to prolonged exclusivity through a species claim for which generic protection has been granted were the patents not commonly owned.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. No claims allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 8, 2007

Celia Chang
Primary Examiner
Art Unit 1625